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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,670	12/11/2003	Richard S. Ginn	15997.4002	6280

34313 7590 01/12/2009
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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01/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,670	Applicant(s) GINN, RICHARD S.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/11/03, 10/25/04, 1/8/07, 12/21/07, 2/21/08, 4/17/08.

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DETAILED ACTION

Election/Restrictions

Applicant's election **without traverse** of species II in the reply filed on 04 November 2008 is acknowledged. No claims have been withdrawn. Claims 1-29 are canceled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 31, 33-63, 65-97, and 101-106 are rejected under 35

U.S.C. 102(e) as being anticipated by **Schreck et al. (U.S. Publication No.**

2002/0107531 A1). Schreck discloses a method for treating a patent foramen ovale (see entire document) comprising the steps of advancing an implantable device (280; for example, see Figure 9B) through the vasculature of a subject via an elongate delivery apparatus comprising a pusher with an actuator (for example, see Figure 10A) and into a first (right) atrial chamber and situating the implantable device within piercings of a first and second tissue flap (piercing is formed by the implantable device) by transitioning a first portion and second portion of the implantable device to a retaining/securing configuration (for

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example, see Figure 10B), wherein first and second tissue flaps overlap and are held in contact, the device also engages the tissue flap in a second (left) atrial chamber to at least partially close the opening (for example, see Figure 10 C), and the retaining configuration is generally coiled and “U” shaped providing a “locking” arrangement. The step of imaging the implantable device is inherent in that such medical procedures are performed under imaging.

Regarding claims 55, 57, 58, 81-85, and 95-97, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 64 and 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Schreck et al.** Schreck discloses the device is advanced through the circulatory system to the heart. To advance the device through the inferior vena cava, superior vena cava, or an artery would have been obvious to one having ordinary skill in the art at the time the invention was made, since the applicant has not disclosed that such vasculature provide an advantage, are used for a particular purpose, or solve a stated problem and it appears the invention would perform equally well if the device were inserted in any other portion of the circulatory system. Furthermore, it is well known in the art to use such vasculature to access the heart.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Schreck et al. in view of Berg et al. (U.S. Patent No. 6,712,836)**. Schreck discloses the claimed invention except for imaging a radiopaque marker on the implantable device with fluoroscopy. Berg et al. discloses a method for closing septal defects (see entire document). Berg discloses the step of imaging a radiopaque marker on the implantable device with fluoroscopy (for example, see column 5, lines 31-35 and claim 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the step of imaging in Schreck's method as taught by Berg. Doing so would enable the operator to assist in the device's placement and also to evaluate the integrity of the device after it has been in use for an extended period of time (for example, see column 5, lines 28-30).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
January 8, 2009

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/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773